Minutes of Meeting

Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

August 11, 2004
1:00 p.m.

Attendees: Richard Freeman, Chair; Rob Colburn, Jackie Feldman, David Herrick, A.Z. Holloway, John Searcy, Ben Main, Dane Yarbrough, Garry Magouirk, Louise Jones, Janelle Sheen

Absent: Jefferson Underwood

(1) OPENING REMARKS
Richard Freeman called the meeting to order and asked that all cell phones and pagers be placed in the off position.

(2) Louise Jones welcomed the Alabama Medicaid Agency Commissioner, Carol Herrmann, and invited her to make a few comments to the P&T Committee and audience.

Carol Herrmann reminded the members of the P&T committee that they must marry high quality, cost efficient services with budget restraints. She said the members carry the brunt of what could be one of the most successful programs of the Agency. Commissioner Herrmann also told each member it is critical that they take to heart their charge: to review the peer reviewed literature, and determine if there are clinically significant advantages with drugs or not. She said it is imperative, and everyone's responsibility to try to help the program be more efficient and cost effective in order to bring services to the greatest amount of people, as Medicaid is about rationing health care. In conclusion, Ms. Herrmann reminded the audience that the state cannot afford the supercharged Volvo or Mercedes and it is very important for the Committee to accept their responsibility, so she doesn't have to consider options down the line without the expert knowledge of the members of the P&T Committee.

(3) Louise Jones gave the pharmacy program update:

Louise Jones discussed the four-brand limit per calendar month. The limit excludes children and all long-term care residents. Covered generic drugs and over-the-counter drugs are excluded and remain available unlimited. The program also excludes antipsychotics and antiretrovirals. There is no savings data available yet, as the program was only implemented in July. The impact of the prescription limit is being monitored.

Ms. Jones reported the Agency has worked with the legislative council on a switchover allowance for certain classes of drugs: antineoplastics, diabetes mellitus, cardiovascular drugs, hemophilia, organ transplant, end-stage renal disease, and hypertension. This option will become effective November 16, 2004, and will allow up to ten brands for recipients whose physicians need to make a treatment switch from one drug to another in the same class during the same month. This option is intended for recipients who would not have been allowed to switch treatments in the same month due to the four-brand limit. Exceptions beyond four brands will only be allowed for this situation and there is a hard cap of ten brands with the limit.

Dane Yarbrough questioned if there would be a DAW code for pharmacists to use, and Louise Jones responded the Agency is working with EDS on this. Louise Jones clarified that the switchover allowance will require an override that would need to be approved through HID.

Louise Jones discussed changes that have been implemented with coverage of cosmetic drugs. Under OBRA 90, cosmetic drugs are an optional coverage group. Drugs that have only FDA-approved indications for cosmetic use will not be covered.

Ms. Jones reported that Alabama Medicaid Agency is continuing to work with Blue Cross Blue Shield and Info Solutions on PDA technology. BCBS and Medicaid claims data will be provided in the PDA. The program will be implemented October 1, 2004.

Ms. Jones indicated the electronic PA process is moving forward. Target implementation is December 1, 2004. The process is expected to eliminate 40% of the current manual prior authorizations.

Ms. Jones announced Town Hall meetings, being held in August and September, for clinical staff. The meetings are not billing seminars. Continuing education programs will be provided for physicians, nurses and pharmacists.

Lastly, Ms. Jones spoke on PDL savings. There have been great savings, but some savings has been affected by consessions for stable therapy. The savings included in the member packets are strictly based on utilization program savings. Additional savings come through supplemental rebates.

Ben Main questioned whether the Agency could consider having longer P&T meetings where more therapy classes are reviewed, in order to bring additional savings to the Agency and speed up the review process. Jackie Feldman commented that she was in agreement and willing to meet more frequently if it would help the Agency with budgetary issues. Louise Jones added that the Agency felt they are close to the end of the classes that needed to be reviewed, and then the re-review process would begin. She also mentioned the Agency is considering outsourcing some of the components that relate to the PDL process (e.g., supplemental rebate negotiation).

(4) Chairman Freeman asked if there were corrections to the minutes. Janelle Sheen commented that Minutes from the May 26, 2004 meeting were revised after the copies were printed for the binder. There were 3 drugs that had manufacturer representatives speak on their behalf that were not included in the minutes: Reminyl, Protonix and Olux. The minutes from the May meeting were approved, motion was extended by Rob Colburn and seconded by A.Z. Holloway.

(5) DOSE SIMPLIFICATION SUMMARY:
Janelle Sheen reported that the Agency requested that clinical literature in the following areas be added to the reviews for the August meeting: dose simplification, stable therapy, impact on physician visits, and additional dosing data.

Ms. Sheen detailed the findings of research into the literature on dose simplification and adherence studies. A meta-analysis showed once daily adherence is 96%, BID is 93%, and TID is 84%. Another study found a mean adherence rate of 76%, with 67% with QID dosing and 85% with BID dosing. She also mentioned at least one study found no difference between QD and BID dosing. Confidence in their provider plays a role in a patient's willingness to comply with treatment, and studies indicate there are more 24-hour periods without any medications with QD therapy than with BID treatment. The conclusion of the research was that the greatest benefit on adherence from dose simplification is from moving QID regimens to QD or BID and from moving TID regimens to QD dosing. Moving forward, all relevant adherence data will be presented in each specific pharmacotherapy review.

Jackie Feldman commented that she appreciated the new information included on adherence for each of the reviews.

(6) PHARMACOTHERAPY REVIEWS (Refer to the web for full text reviews):
Section I. Antidiabetic Agents (AHFS Classes 682002, 682004, 682008, 682016, 682020, 682028)

Oral Presentations by Manufacturers/Manufacturer's Representatives and Drug Class reviews began at approximately 1:30 p.m. Three-minute verbal presentations were made on the following drugs by, or on behalf of, Pharmaceutical Manufacturers:

Manufacturer comments on behalf of these products:
Lantus, Novolog, Actos

Ms. Sheen began the Antidiabetic Agents with the α-Glucosidase Inhibitor review. She said there are two agents available in this class: acarbose and miglitol. No additional clinical information was presented. All brand products within the α-glucosidase inhibitor class are comparable to each other and offer no significant clinical advantage over other alternatives in general use. No brand α-glucosidase inhibitor is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the biguanides, which includes the metformin products. Riomet (metformin oral solution) is newly available for review and is bioequivalent to metformin tablets. Since the May 2004 review, there is a new generic metformin extended-release formulation, in a 500mg tablet. All brand products within the class reviewed are comparable to each other and to the generics in this class and offer no significant clinical advantage over other alternatives in general use. No brand biguanide is recommended for preferred status.

Jackie Feldman asked what percentage of patients on metformin XR use more than one tablet. Janelle Sheen commented that in studies with metformin XR, patients received 1000mg and 1500mg doses. Dr. Feldman agreed that the once-daily dosing was a significant advantage of the extended-release products.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the insulins and clarified that all OTC insulins are covered by the Agency and the review and recommendations should pertain to the remaining prescription agents: Novolog and Humalog products, Lantus, and Humulin R U-500. Ms. Sheen highlighted the indications, comparative adverse events, and efficacy information of the prescription insulins, stating information from various studies and manufacturers recommendations. Additionally, she reported that no studies have looked at adherence with once-daily insulin glargine (Lantus) and impact on HbA1c. Therefore, all brand products within the class are comparable to each other and offer no significant clinical advantage over other alternatives in general use. No brand prescription insulin is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the meglitinides including repaglinide and nateglinide. No new information was presented. The conclusion and recommendation was made: all brand products within the meglitinide class are comparable to each other and offer no significant clinical advantage over other alternatives in general use. No brand meglitinide is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the sulfonylurea agents. Little new clinical information was presented. One adherence study evaluated QD and BID therapy with glipizide and found adherence rates of 60.5% vs. 52% and 44% vs.36% at 12 months, for QD vs. BID therapy. All brand products within the class reviewed are comparable to each other and to the generics in the sulfonylurea class and offer no significant advantage over other alternatives in general use. No brand sulfonylurea is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the thiazolidinediones, pioglitazone and rosiglitazone. Limited new data was presented. Ms. Sheen added that research was done looking at stable therapy with this class of drugs, and no data was found. The drugs within the thiazolidinedione class offer significant clinical advantage in general use but are comparable to each other. Medicaid should work with manufacturers of pioglitazone (Actos®) and rosiglitazone (Avandia®) on cost proposals so that at least one brand of pioglitazone or rosiglitazone is selected as a preferred agent.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the antidiabetic combination agents and stated that since the May 2004 meeting a generic metformin/glyburide product has become available. She also reported that comparative studies evaluating the fixed-dose combination agents with the respective monotherapies has been limited, but more studies are now being published. Multiple studies support the use of the fixed-dose metformin/glyburide product over glyburide co-administered with metformin, due to benefits on HbA1c. All brand products within the class reviewed are comparable to each other and offer no significant advantage over other alternatives in general use. No brand combination diabetes agent is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

(7) PHARMACOTHERAPY REVIEWS (Refer to the web for full text reviews): Section II. Alzheimer's Agents (AHFS Class 120400, and 289200).

Manufacturer comments on behalf of these products:
Aricept, Reminyl, Namenda

Janelle Sheen reported that memantine (Namenda) is newly eligible for review in this class and is indicated for moderate to severe dementia of the Alzheimer's type. Based on memantine's indication, the drug is useful for patients who have tried and failed cholinesterase inhibitors or whose cognitive disease continues to progress. Ms. Sheen also added that clinical efficacy data for the agents in this class continues to be mixed. Further discussion centered on stable therapy. Limited literature is available through Medline and Ovid on practice guidelines for switching cholinesterase inhibitors. What evidence is available suggests a washout period should be considered, especially in cases where patients have experienced poor tolerability. The conclusion was made that donepezil, rivastigmine, and galantamine offer significant clinical advantage in general use over the generics and OTC products but are comparable to each other. Additionally, tacrine (Cognex) possesses an extensive adverse effect profile. Alabama Medicaid should work with the manufacturers of the brands of donepezil, rivastigmine, and galantamine on cost proposals so that at least one brand is placed in preferred status. No brand of memantine is recommended for preferred status. Brand products of tacrine (Cognex) should not be placed in preferred status regardless of cost.

Jackie Feldman had comments pertaining to discussion from the May 2004 meeting. She discussed some of the advantages of dosing and stable therapy. Richard Freeman clarified how amendments are to be made during the meeting. Dr. Magouirk explained that enough evidence was presented that the three cholinesterase inhibitors are equal in efficacy and the PA process could handle those recipients who needed a non-preferred agent. Dr. Holloway questioned, and Dr. Feldman confirmed the same question, as to whether the Agency would allow patients in this class to remain on the drug they were stabilized on. Dr. Searcy confirmed that the Agency has considered this and will allow recipients who have been on these drugs to continue on the same agents. Dr. Feldman questioned whether memantine was included in this and if a PA process would be available for memantine. Dr. Searcy answered that the PA process would handle memantine as well and it would be considered for continued therapy.

Richard Freeman asked the Committee to mark their ballots.

(8) PHARMACOTHERAPY REVIEWS (Refer to the web for full text reviews):
Section III. Proton Pump Inhibitors (AHFS Class 562836).

Manufacturer comments on behalf of these products:
Nexium, Prevacid

Janelle Sheen discussed the proton pump inhibitors (PPI) and noted that there is a newly approved omeprazole powder for oral suspension (Rapinex). She commented that unique administration information and pediatric indication information had been updated in the August 2004 materials, but this unique administration did not represent general use of these agents. Ms. Sheen also mentioned that little data is available on stable therapy in this class. All brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. The recommendation made was that no brand proton pump inhibitor is recommended for preferred status.

Dr. Feldman commented that she didn't agree that the agents in the class were comparable if only two were indicated for use in children. Dr. Holloway asked if the Committee could amend the recommendation so that at least one drug with a pediatric indication would be on the PDL. There was discussion about obtaining a prior authorization and several members commented they had not had previous problems with obtaining these authorizations. No specific motion was made to amend the recommendation.

Richard Freeman asked the Committee to mark their ballots.

(9) PHARMACOTHERAPY REVIEWS (Refer to the web for full text reviews): Section IV. Skin and Mucous Membrane Agents (AHFS Classes 840404, 840406, 840408, 840412, 840416, 840600, 840800, 841200, 842800, 843200, 843600).

Manufacturer comments on behalf of these products:
Pandel, Gynazole-1, Protopic, DermaSmooth FS Scalp Oil, and DermaSmooth FS Eczema Oil

Janelle Sheen reported there was no additional information to present to the Committee in this class. Clindamycin and metronidazole vaginal agents offer significant clinical advantage in general use over the generics and OTC products but are comparable to all other brands in this class. However, the remaining agents in the topical antibacterial class are comparable to each other and to the generics and OTC products in this class and offer no significant clinical advantage over other alternatives in general use. Alabama Medicaid should work with the manufacturers of the brands of clindamycin vaginal and metronidazole vaginal on cost proposals so that at least one brand is selected as a preferred agent. In addition, there is no brand recommended for preferred status of the remaining antibacterial agents in this class.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the topical antivirals, which include acyclovir and penciclovir. No additional clinical data was presented. All brand products within the topical antiviral class are comparable to each other and to the generics and OTC products in this class and offer no significant clinical advantage over other alternatives in general use. No brand topical antiviral is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the topical antifungals and stated that this class includes 18 different agents with different indications. She clarified that there are OTC one-time vaginal antifungal products, and a generic is available. All brand products within the class reviewed are comparable to each other and to the generics and OTC products in the antifungal class and offer no significant clinical advantage over other alternatives in general use. No brand topical antifungal is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the scabicides and pediculocides and stated that no new clinical information needed to be presented since discussion at the May 2004 meeting. The permethrin products within this class offer significant clinical advantage in general use over the other brands, generics and OTC products in the same class, but are comparable to each other. Additionally, lindane possesses an extensive adverse effect profile. Because generic and over-the-counter permethrin products are available, no brand of permethrin is recommended for preferred status. At this time, no brand lindane product is available; however, should one become available, it should not be placed in preferred status regardless of cost.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the miscellaneous local antiinfectives and stated that these agents are primarily used for burn care and antiseptic cleansing. No new clinical information was presented for the agents in this class. All brand products within the miscellaneous local antiinfectives class reviewed are comparable to each other and to the generics and OTC products in this class and offer no significant clinical advantage over other alternatives in general use. No brand miscellaneous local antiinfective is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the antiinflammatory agents, but had no new clinical data to present. She gave the conclusion and recommendation: all brand products within the class reviewed are comparable to each other and to the generics and OTC products in the topical anti-inflammatory agents class and offer no significant advantage over other alternatives in general use. No brand topical corticosteroid is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the topical antipruritics, which are under the chemical entity doxepin and the brand names Prudoxin and Zonalon. There was no new clinical information to report and the conclusion and recommendation was given: all brands within the class reviewed are comparable to each other and to the generics and OTC products and offer no significant clinical advantage over other alternatives in general use. No brand topical antipruritic is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen reported that the topical astringents are primarily indicated for the treatment of hyperhidrosis. No new data was presented. All brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand astringent is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the topical keratolytics, which include urea and podophyllum resin products. There was clarification that the Carmol scalp combination product (urea plus sulfacetamide) was not included in this review. Ms. Sheen reported data found in the literature on physician visits for the treatment of genital warts. Literature suggests that the average episodes of care for this condition involve 3.1 physician visits. One study comparing the different treatments showed the surgical methods of wart removal and podofilox were associated with lower utilization of medical services. Surgical therapies are often associated with higher rates of wart recurrence. Imiquimod and podophyllotoxin clearance rates are similar, however, imiquimod is associated with lower recurrence rates. All brand products in the keratolytic class are comparable to each other (the urea products and the podophyllin products) and to the generics and OTC products in this class and offer no significant clinical advantage over other alternatives in general use. No brand keratolytic is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the topical keratoplastic agents, which include coal tar and anthralin products. Clarification was made on how the benefits of coal tar were discovered. Scientists studying the drug's carcinogenic properties in mice noticed that application to the skin resulted in improvements in certain skin conditions. All brand products within the keratoplastic class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand keratoplastic agent is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Janelle Sheen discussed the topical miscellaneous skin and mucous membrane agents, and commented that imiquimod has a new indication for superficial basel cell carcinoma. Clarification was also made as to the indications for pimecrolimus and tacrolimus. No further new information was discussed.

When comparing agents within the topical miscellaneous skin and mucous membrane agent class, alitretinoin, becaplermin, bexarotene, collagenase, diclofenac sodium, and fibrinolysin w/desoxyribonuclease offer significant clinical advantage when used for their respective treatment indications. At this time, there is no role for these agents in general use. Because these six medications have narrow indications with limited usage, they should be available for special needs/circumstances that require medical justification through the prior authorization process. After clinical circumstances are explored, proper medical justification will provide patient access to these agents. However, the remaining agents in this class are comparable to each other and to the generics and OTC products in this class and offer no significant clinical advantage over other alternative in general use. No brand miscellaneous skin and mucous membrane agent is recommended for preferred status.

Richard Freeman asked the Committee to mark their ballots.

Richard Freeman initiated a break at 2:25 p.m., which lasted 5 minutes.

(10) NEW DRUG REVIEWS (Refer to the web for full text reviews):
Eplerenone – Mineralocorticoids (Aldosterone) Receptor Antagonist (AHFS Class 402800)

Manufacturer comments on behalf of this product:
Inspra

Janelle Sheen reported that the only new clinical data to be presented pertains to pediatric use. The safety and efficacy of eplerenone has not been established in pediatric patients, while spironolactone is indicated in children and has been studied in the pediatric population. Ms. Sheen made the following conclusion and recommendation: eplerenone (Inspra) is comparable to the other brands in this class and to the generics and OTC products in this class and offers no significant clinical advantage over other alternatives in general use. No brand of eplerenone is recommended for preferred status.

Jackie Feldman discussed study results with eplerenone that showed lowered hospitalizations. Ms. Sheen commented that the best clinical evidence can be obtained by looking at comparative evidence of the drugs in a class. Dr. Holloway questioned Dr. Magouirk as to the use of eplerenone as a first-line agent. The members agreed that eplerenone would have availability through prior authorization.

Richard Freeman asked the Committee to mark their ballots.

Rosuvastatin – HMG CoA Reductase Inhibitors (AHFS Class 240608)

Manufacturer comments on behalf of these products:
Crestor

Janelle Sheen reported to the Committee that new cholesterol guidelines were announced on July 13, 2004. The new guidelines establish a group of patients at very high risk (e.g., history of CAD, diabetes, metabolic syndrome, MI) and lower the goal LDL from <100mg/dl to <70mg/dl. Also, since the May 2004 meeting, the FDA has issued a Public Health Advisory warning about the use of the drug in high risk patients with predisposing factors for myopathy. The warning stresses that physicians follow all manufacturers recommendations, especially for dosing, and explains that the FDA is evaluating reports of muscle effects with rosuvastatin.

Ms. Sheen reported safety data for the 80mg rosuvastatin dose. The 80mg dosage form is no longer available, but has a high frequency of creatine kinase elevations, between what was seen in clinical trials for cerivastatin, and higher than seen for all other currently approved statins. The 80mg dose also has a higher incidence of myopathy and rhabdomyolysis observed in clinical trials than reported in the original New Drug Application of labels for any of the currently approved statins. Additionally, rosuvastatin has been associated with renal findings (proteinuria and hematuria) not seen with other statins. Finally, Ms. Sheen reported that the rate of reports of rhabdomyolysis per million U.S. prescriptions when compared for fluvastatin, lovastatin, simvastatin, and atorvastatin, to rosuvastatin, is higher than the highest of any other currently marketed statin.

A conclusion was made that until rosuvastatin's safety can be established, the drug should be reserved for, and used with caution in, only those patients who have not responded adequately to statins with a longer safety record. The treatment of hyperlipidemia in this population should be considered unique and not within the scope of the general use of the drugs within this class. Therefore, rosuvastatin is comparable to the other brands in this class and to the generics and OTC products in this class and offers no significant advantage over other alternatives in general use. No brand of rosuvastatin is recommended for preferred status.

Dr. Freeman asked what doses of rosuvastatin had been reported as having caused the renal problems and Ms. Sheen responded that the literature only reported that proteinuria and hematuria had occurred primarily with "higher doses," and did not provide specific information. Additionally, Ms. Sheen clarified that the higher incidence of myopathy reported in the presentation was specific to the 80mg dose and no specific data is available for the 5mg or 10mg doses. Dr. Magouirk commented that other statin drugs at higher doses provide similar cholesterol reductions as rosuvastatin at 5mg-10mg, and should be used first. He also stated that rosuvastatin does not bring anything new to the table in comparison to the other statin drugs. Ben Main proposed discussing rosuvastatin in the future. Ms. Sheen responded that this class as a whole would be re-reviewed. No amendments were made to the recommendation.

Richard Freeman asked the Committee to mark their ballots.

(11) ANTIDEPRESSANT WARNING UPDATE

Janelle Sheen announced that the FDA has not formally released new information on antidepressant use in children since the data was reported for the May 2004 P&T meeting. More information is expected to be announced from the FDA this summer. Jackie Feldman added that she saw an update recently that indicated the findings may not be positive when they are formally announced.

ACS-Heritage will provide updates to the Agency when they are available.

(12) CLOSING REMARKS

The next P&T meeting will be held on October 27, 2004 at 1:00 p.m. Richard Freeman adjourned the meeting at 3:29 p.m.

(13) RESULTS OF THE BALLOTING

A. The P&T Committee voted unanimously to accept the recommendation that no brand α-Glucosidase Inhibitor is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☒ Approve	☐ Deny	☐ Approve with modification

B. The P&T Committee voted unanimously to accept the recommendation that no brand biguanide is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☒ Approve	☐ Deny	☐ Approve with modification

C. The P&T Committee voted unanimously to accept the recommendation that no brand insulin is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☒ Approve	☐ Deny	☐ Approve with modification

D. The P&T Committee voted to accept the recommendation that no brand meglitinide is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☒ Approve	☐ Deny	☐ Approve with modification

E. The P&T Committee voted unanimously to accept the recommendation that no brand sulfonylurea product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☒ Approve	☐ Deny	☐ Approve with modification

F. The P&T Committee voted unanimously to accept the recommendation that Medicaid should work with the manufacturers of pioglitazone (Actos) and rosiglitazone (Avandia), on cost proposals so that at least one of the recommended brands is selected as a preferred agent. Medicaid should accept cost proposals from the manufacturers of pioglitazone (Actos) and rosiglitazone (Avandia) so that as least one of the recommended products is selected as a preferred agent.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification
Commissioner	☒ Approve	☐ Deny	☐ Approve with modification

G. The P&T Committee voted unanimously to accept the recommendation that no brand antidiabetic combination agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director — ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner — ☒ Approve ☐ Deny ☐ Approve with modification

H. The P&T Committee voted unanimously to accept the recommendation that donepezil, rivastigmine, and galantamine offer significant clinical advantage in general use over the generics and OTC products but are comparable to each other. Medicaid should accept cost proposals from the manufacturers of the brands of donepezil, rivastigmine, and galantamine so that at least one brand is placed in preferred status. No brand of memantine is recommended for preferred status. Brand products of tacrine should not be placed in preferred status regardless of cost.

Medical Director — ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner — ☒ Approve ☐ Deny ☐ Approve with modification

I. The P&T Committee voted unanimously to accept the recommendation that no brand proton pump inhibitor product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director — ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner — ☒ Approve ☐ Deny ☐ Approve with modification

J. The P&T Committee voted unanimously to accept the recommendation that Medicaid should work with manufacturers of the recommended brands of antibacterial agents, clindamycin vaginal and metronidazole vaginal, on cost proposals so that at least one of the recommended brands is selected as a preferred agent. In addition, there is no brand recommended for preferred status of the remaining antibacterial agents in this class. Medicaid should accept cost proposals from the manufacturers of the brands of clindamycin vaginal and metronidazole vaginal so that at least one brand is selected as a preferred agent. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred brands for the remaining antibacterial agents in the class.

Medical Director — ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner — ☒ Approve ☐ Deny ☐ Approve with modification

K. The P&T Committee voted unanimously to accept the recommendation that no brand topical antiviral is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director — ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner — ☒ Approve ☐ Deny ☐ Approve with modification

L. The P&T Committee voted unanimously to accept the recommendation that no brand topical antifungal is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director — ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner — ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner — ☒ — —

☐ Approve ☐ Deny ☐ Approve with modification

Commissioner

M. The P&T Committee voted unanimously to accept the recommendation that because generic and over-the-counter permethrin products are available, no brand of permethrin is recommended for preferred status. Additionally, at this time, no brand lindane product is available; however, should one become available, it should not be placed in preferred status regardless of cost. Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands. Furthermore, the P&T Committee voted to accept the recommendation that lindane products possesses an extensive adverse effect profile or is clinically inferior to the other brand, generics and OTC products. Lindane should not be given preferred status regardless of cost.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

N. The P&T Committee voted unanimously to accept the recommendation that no brand miscellaneous local anti-infective products is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

O. The P&T Committee voted unanimously to accept the recommendation that no brand topical corticosteroid is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner ☒ Approve ☐ Deny ☐ Approve with modification

P. The P&T Committee voted unanimously to accept the recommendation that no brand topical antipruritic agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner ☒ Approve ☐ Deny ☐ Approve with modification

Q. The P&T Committee voted unanimously to accept the recommendation that no brand astringent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner ☒ Approve ☐ Deny ☐ Approve with modification

R. The P&T Committee voted unanimously to accept the recommendation that no brand keratolytic agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner ☒ Approve ☐ Deny ☐ Approve with modification

S. The P&T Committee voted unanimously to accept the recommendation that no brand keratoplastic agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

T. The P&T Committee voted unanimously to accept the recommendation that no brand miscellaneous skin and mucous membrane agent is recommended for preferred status. Alabama Medicaid will consider the availability of alitretinoin, becaplermin, bexarotene, collagenase, diclofenac sodium, and fibrinolysin with desoxyribonuclease for special needs/circumstances that require medical justification through the prior authorization process. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more of the remaining agents in this class as preferred.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

U. The P&T Committee voted to accept the recommendation that no brand of eplerenone is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

V. The P&T Committee voted to accept the recommendation that no brand of rosuvastatin is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

Commissioner ☑ Approve ☐ Deny ☐ Approve with modification

Respectfully submitted,

Janelle Sheen 8-31-2004

Janelle Sheen Date